RATIONALE FOR THE DEVELOPMENT OF ONTARIO AIR STANDARDS FOR METHYLENE CHLORIDE

CONSULTATION DRAFT

February 1998

Standards Development Branch
Ontario Ministry of the Environment

Ontario

Executive Summary

The Ontario Ministry of the Environment has identified the need to develop and/or update air quality standards for priority contaminants. The Ministry's Standards Plan which was released in October 1996, identified candidate substances for the development of air standards for the next several years (MOEE, 1996). Methylene chloride was identified as priority for review based both on its pattern of use in Ontario and recent toxicological information published since the existing standard was developed in 1988.

Methylene chloride is a volatile, colourless liquid with a mildly sweet odour. It is widely used in paint removers, as a solvent for plastics, as a degreasing agent, in propellant mixtures for aerosol containers and as pharmaceutical intermediates. In a survey between 1989 and 1991, 24-hour average concentrations measured at Ontario air quality monitoring sites ranged from 0.7 to 5.6 $\mu g/m^3$ (micrograms of methylene chloride per cubic metre of air). The maximum level measured in 1991 was 22.9 $\mu g/m^3$ at a site in Hamilton. Average methylene chloride concentrations at sites across Canada range from 0.5 to 9.9 $\mu g/m^3$.

There is sufficient evidence to consider methylene chloride as an animal carcinogen with the liver and lungs as the main target organs. Other organs affected include the mammary and salivary glands. Human health data from epidemiological studies do not provide consistent evidence of carcinogenicity in humans. However, increases of melanoma (a type of tumour) and cancers in the buccal (mouth) cavity and pharynx, liver and biliary passages, and the breast have been observed in some workers exposed to methylene chloride and other solvents. Information obtained from studies of animals subjected to short-term exposure to methylene chloride, suggest that detrimental effects other than cancer may be induced. These include adverse effects on the central nervous system, liver, heart, lungs and the kidneys. In longer term exposure studies, adverse effects in the liver, kidney and brain tissues have been reported.

The current Ontario standards for methylene chloride are as follows: the interim half-hour Point-of-Impingement standard is 5300 $\mu g/m^3$, while the 24-hour average Ambient Air Quality Criterion is 1765 $\mu g/m^3$ Both of these are based on non-cancer human health effects. More recent toxicological information suggests that methylene chloride should be treated as a probable human carcinogen. Based on this information, the current Ontario standards developed in 1988 are now considered to be in need of review.

In developing air quality standards for Ontario, the Ministry of the Environment is reviewing and considering air quality guidelines and standards used by environmental agencies world-wide. A number of agencies including the United States Environmental Protection Agency, the California Department of Health Services, the Department of Environmental Protection of the Commonwealth of Massachusetts as well as Health and Environment Canada, under the *Canadian Environmental Protection Act*, have developed cancer risk estimates for methylene chloride. Among these agencies, the assessment conducted by Health Canada was judged to have

the most appropriate rationale and was used as the basis for recommending revised air quality standards for methylene chloride for Ontario.

Methylene chloride has been assessed as toxic under the Canadian Environmental Protection Act. To minimize environmental releases of methylene chloride, Environment Canada is developing a management strategy under its Strategic Options Process to reduce the use and emission of methylene chloride in a variety of industrial processes and commercial products. Sectors participating in the Strategic Options Process have agreed in principle to reduce the use and release of methylene chloride by 50-90% by the year 2002 with further reductions being considered beyond that date.

Based on the evaluation of recent toxicological information; the ambient air quality guidelines used in other jurisdictions; modelled ground level concentrations from recent applications for Certificates of Approval; the on-going federal Strategic Option Process and the levels of methylene chloride measured in Ontario, the Ministry is proposing:

- an annual average Ambient Air Quality Criterion for methylene chloride of 44 $\mu g/m^3$ (micrograms of methylene chloride per cubic metre of air). This value is based on the health assessment conducted by Health Canada and corresponds to an excess lifetime cancer risk of approximately 1 in 1,000,000;

- a revision of the existing 24-hour Ambient Air Quality Criterion for methylene chloride from its current level of 1765 $\mu g/m^3$ to 220 $\mu g/m^3$.

In light of the reduction strategies for methylene chloride being developed under the Canadian Environmental Protection Act, the Ministry is seeking additional information from stakeholders prior to recommending a revised point-of-impingement standard for this compound. The Ministry is asking Ontario sources of methylene chloride to assess the emission reductions being anticipated as a result of strategies being developed under the Canadian Environmental Protection Act. This information will be considered in setting a point-of-impingement standard for methylene chloride to be implemented on a timetable consistent with the recommendations under the Strategic Options Process.

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1.0 Introduction

Ontario's primary approach to regulating air emissions is based on achieving and maintaining air quality which is protective of human health and the environment. The *Environmental Protection Act* requires all stationary sources which emit or have the potential to emit a contaminant to obtain a Certificate of Approval which outlines the conditions under which the facility can operate.

Compliance with air quality standards and guidelines is one of the criteria used to issue Certificates of Approval. Sources or potential sources of a contaminant are required to control emissions to ensure that the concentration of a contaminant specified by the standard is not exceeded at any point off their property. Dispersion modelling which incorporates detailed engineering calculations is used to relate emission rates from a source to resulting ambient concentrations of a particular contaminant.

The Ministry of the Environment uses a combination of regulatory standards, ambient air quality criteria (AAQCs) and point-of-impingement (POI) guidelines in reviewing Certificates of Approval (MOEE, 1994a). Point of impingement standards are established under Regulation 346 and can be used directly as enforcement tools as the regulation specifies that a source cannot emit a contaminant at a level which would result in a standard being exceeded at its maximal point of impingement off its property (Section 5(3)). All sources are required to comply with Regulation 346 POI standards unless they are specifically exempted in regulation. As POI standards specified under Regulation 346 apply to all sources, socio-economic issues need to be taken into consideration in their development to ensure that the standards are technically feasible and there is a balance between the benefits and costs of improved ambient air quality.

In addition to POI standards established under Regulation 346, the Ministry also has a larger number of ambient air quality criteria and point of impingement guidelines which are derived from AAQCs. These are used by the Ministry to assess general air quality and the *potential* for causing an adverse effect (MOEE 1994). Like POI standards specified in Regulation 346, point of impingement guidelines are also used in Certificates of Approval to approve new and modified emission sources. Once incorporated into a legal instrument like a Certificate of Approval, point of impingement guidelines are legally binding, however unlike Regulation 346 POI standards, they do not automatically apply to existing sources at the time they are promulgated. AAQCs are normally set at a level not expected to cause adverse human health or environmental effects based on continuous exposure. As such, socio-economic factors such as technical feasibility and costs are not explicitly considered when establishing such limits.

Generally, point-of-impingement standards and guidelines which employ half-hour averaging times are set such that compliance with the standard or guideline will ensure that the Ambient Air Quality Criterion which is based on longer term averaging periods (e.g. 24-hours) will be met. In certain cases where the effect can occur over short-term exposures, like odours, the 24-hour

Ambient Air Quality Criterion and the half-hour point-of-impingement standard may have the same value.

The Ontario Ministry of the Environment has identified the need to develop and/or update air guidelines/standards for priority toxic contaminants. The Ministry's Standards Plan which was released in October 1996, identified candidate substances for the development of air standards for the next several years. Methylene chloride was identified as a priority for review based both on its pattern of use in Ontario and recent toxicological information published since the existing standards were developed in 1988. This document provides the rationale for recommending revised AAQCs for methylene chloride.

2.0 Review and Evaluation

2.1 General Information

Methylene chloride (CH_2Cl_2), also known as dichloromethane, is a volatile, colourless liquid with a mildly sweet odour. The odour threshold of methylene chloride ranges from 25 ppm to 150 ppm; at above 350 ppm, most people can detect the odour. This chemical readily vaporizes at ambient temperature. The Chemical Abstracts Service (CAS) identification number is 75-09-2, the Registry of Toxic Effects of Chemical Substances (RTECS) number is 805000 and the United Nations Hazardous Material number is 1593.

At high concentrations in the workplace, methylene chloride has been observed to result in adverse effects on the nervous system, including dizziness, headache, irritability, numbness and tingling in the limbs; fatigue, stupor and rare reports of death due to anaesthesia. Eye and respiratory irritation and upset stomach have also been reported. At lower and chronic exposure, liver disease is the primary adverse effect reported. In addition, it has been reported that metabolism of methylene chloride within the human body results in the production of carbon monoxide, with a resulting increase in carboxyhemoglobin (COHb), which can have an adverse effect associated with oxygen deficiency. Subchronic and chronic laboratory studies on rats have confirmed the observations in humans of liver effects and the increase in carboxyhemoglobin from exposure to methylene chloride. No adverse effects on development or reproduction were observed in studies on rats and mice (Environment Canada and Health Canada, 1993; ACGIH, 1991; CARB, 1989).

According to the International Agency for Research on Cancer (IARC; 1987) and the United States Environmental Protection Agency (U.S. EPA, 1997), the evidence from studies available in the workplace is inadequate to characterize methylene chloride as carcinogenic to humans. Exposure to rats and mice by inhalation increased the incidence of benign and malignant lung and liver tumours in mice and benign mammary tumours in rats. The evidence for carcinogenicity in laboratory animal studies was therefore considered sufficient for classifying methylene chloride as

a probable human carcinogen by both the International Agency for Research on Cancer (IARC Group 2B) and U.S. EPA (Group B2).

2.2 Sources and Levels

Methylene chloride is widely used as an active chemical in paint removers, as a solvent for plastics, as a degreasing agent, in propellant mixtures for aerosol containers and as a blowing agent in foams. It is also used in photoresistant stripping operations, in film processing and as an extraction solvent for spice oleoresins and hops, for the removal of caffeine from coffee, and as pharmaceutical intermediates (ACGIH, 1991; Environment Canada and Health Canada, 1993). Methylene chloride is not manufactured in Canada. In 1995, of the 8500 tonnes imported (7,500 tonnes as a neat chemical, 600 tonnes in formulated products and 400 tonnes as recycled solvents) about 7400 tonnes were used in Canada whereas about 1200 tonnes were exported. Environmental releases to the atmosphere were about 6300 tonnes or 85% of the total quantities used (Environment Canada and Health Canada, 1997). Based on the summary reports of the Canadian National Pollutants Release Inventory (NPRI), the total releases of methylene chloride in Canada had almost doubled from 1322 tonnes in 1993 to 2222 and 2207 tonnes in 1994 and 1995, respectively (NPRI 1993, 1994 & 1995). The total releases in Ontario showed a similar pattern. In 1993, 924 tonnes of methylene chloride were released, whereas this amount had increased to 1613 and 1610 tonnes in 1994 and 1995, respectively. The 1995 NPRI report listed 28 sources of atmospheric release of methylene chloride in Ontario. The vast majority of these releases were from foam and expanded plastics operations and pharmaceutical uses, a few covered such activities as adhesives and paint stripping uses, office furniture manufacturing and as industrial and household chemicals.

An analysis of recent applications for Certificates of Approval in Ontario identified 56 facilities with emissions of methylene chloride covered by a Certificate. The majority of these approvals were for emissions from paint stripping and spray paint uses, foam and expanded plastics operations and pharmaceutical manufacturing. A few covered such uses as cleaning solvents, adhesives and in office furniture manufacturing. The median Ground Level Concentration predicted by Regulation 346 dispersion modelling for all 56 sources was approximately 61 $\mu g/m^3$. The maximum and minimum were 72127 and 0.00049 $\mu g/m^3$, respectively. Eleven sources had predicted ground level concentrations above 500 $\mu g/m^3$.

Average 24-hour concentrations at Ontario sites ranged between 0.7 $\mu g/m^3$ and 5.6 $\mu g/m^3$ over the period of 1989 to 1991. Maximum levels of methylene chloride measured in Ontario in 1991 ranged from 1.6 $\mu g/m^3$ at Walpole Island to 22.9 $\mu g/m^3$ at Hamilton. The three highest 24-hour average concentrations in Sarnia in 1996, as reported by the Lambton Industrial Society, ranged from 6.3 to 12.1 $\mu g/m^3$. The highest annual average levels were observed in North York in 1989 (3.4 $\mu g/m^3$) and in Hamilton in 1990 and 1991 (5.6 and 5.3 $\mu g/m^3$, respectively) (MOEE, 1993).

Across Canada, average methylene chloride levels range from 0.5 to 9.9 $\mu g/m^3$. The national mean was 1.7 and 2.6 $\mu g/m^3$ in two separate studies (Environment Canada and Health Canada, 1993). According to the Hazardous Substances Database (HSDB) (1996), in 1979, background concentrations in the Northern Hemisphere were reported to be 44 parts per trillion (0.16 $\mu g/m^3$) and in the Southern Hemisphere, 20 parts per trillion (0.07 $\mu g/m^3$). In the United States, in 1982, rural/remote areas were reported to be in the range of 45 parts per trillion (0.16 $\mu g/m^3$). Urban/suburban areas ranged from 414 to 12,000 parts per trillion (1.46 - 42 $\mu g/m^3$), with an average across 718 samples of 630 parts per trillion (2.2 $\mu g/m^3$). In source-dominated areas in the United States, concentrations ranged from 10 to 74000 parts per trillion (0.04 - 261 $\mu g/m^3$).

2.3 Review of Existing Air Quality Regulations

Agency-specific summaries of information concerning air quality guidelines for methylene chloride are presented in the Appendix of this report. A brief summary is presented in Table 1.

2.4 Development of Strategic Options for the Management of Methylene Chloride under the Canadian Environmental Protection Act (CEPA)

Methylene chloride has been assessed as toxic under the *Canadian Environmental Protection Act* (CEPA). As such, Environment Canada is obliged to develop options to minimize the environmental release of this compound from all points in its life cycle in order to minimize exposure and the potential environmental and health risk. To develop management options for methylene chloride, Environment Canada has initiated a Strategic Options Process (SOP) to examine the options available for reducing the uses of this substance in the manufacturing of flexible foam, pharmaceuticals and adhesives as well as in paint stripping and some minor applications (CEPA, 1997). The SOP Issue Table is made up of representatives from government, industry and environmental non-governmental organizations. Issues being considered include the technical feasibility and cost of reducing methylene chloride usage in each sector and the benefits of such measures. Also considered are initiatives on-going in other jurisdictions such as the development of National Emission Standards for Hazardous Air Pollutants by the U.S. EPA.

In a recent draft report members of the Issue Table agreed in principle to the following emission reduction targets for methylene chloride:

- in aircraft paint stripping applications, a 50% reduction in annual emission by the year 2002 and 80% by 2006; the use of methylene chloride in consumer and commercial paint stripping applications and aerosols applications to be reduced by 20% of the 1995 levels;

Table 1. Summary of Existing Air Quality Guidelines[1] for Methylene Chloride

Agency, Date[2]	Guideline(s)[3]		Comments
U.S. EPA (IRIS) 1997	no ambient air exposure limits are available		
	20 µg/m^3 2 µg/m^3	(lifetime exposure) (lifetime exposure)	1*10^{-5} additional cancer risk 1*10^{-6} additional cancer risk Both are based on a unit risk of 0.00000047 tumours/(µg/m^3)
California 1993	3500 µg/m^3 3000 µg/m^3 300 µg/m^3	(acute exposure) (inhalation reference exposure level) (proposed chronic REL; OEHHA, 1997)	non-cancer acute exposure; inhalation reference exposure for non-cancer risks; (proposed REL based on effects on cardiovascular and nervous systems)
	10 µg/m^3 1 µg/m^3	(lifetime exposure) (lifetime exposure)	1*10^{-5} additional cancer risk 1*10^{-6} additional cancer risk Both are based on a unit risk of 0.000001 tumours/(µg/m^3) and risk levels of
WHO 1987	3000 µg/m^3	(24-hour average)	based on extrapolation from occupational exposure limits
Netherlands 1987	350000 µg/m^3 20 µg/m^3 7.5 µg/m^3	(maximum acceptable concentration) (target value) (maximum emission concentration)	MAC is an occupational guideline; target based on risk assessment in Dutch
Sweden[4] 1993	350 µg/m^3	(long-term average)	safety factor of 5000 applied to LOEC from animal carcinogenicity tests
New York 1990	41000 µg/m^3	(1-hour average)	1-hour average based on occupational exposure limits;
	27 µg/m^3	(annual average)	1*10^{-6} additional cancer risk based on a unit risk of 0.000000037 tumours/(µg/m^3)
Massachusetts 1990	9.45 µg/m^3	(24-hour ceiling limit)	24-hour limit based on occupational exposure limit;
	0.24 µg/m^3	(allowable ambient limit)	1*10^{-6} additional cancer risk based on a unit risk of 0.0000041 tumours/(µg/m^3)
Health Canada	2200 mg/m^3	(Tumorigenic Concentration 05)	5% increase in incidence or mortality due to tumours
Ontario (current) 1988	5300 µg/m^3 1765 µg/m^3	(half-hour point of impingement limit) (24-hour limit)	point of impingement limiting effect and AAQC limiting effect both based on health

1. Guidelines in this table can refer to: guidelines, risk-specific concentrations based on cancer potencies, and non-cancer-based reference concentrations.
2. Date here refers to when the health-based guideline background report or original legislative initiative was issued. The sources were the respective agency documents.
3. Using conditions of 1 atmosphere and 10°C, 1.0 µg/m^3 = 0. 274 ppb. Various agencies use conversion factors based on a range of temperatures, varying between 0°C to 25°C. Depending on the selected temperature, conversion of units may vary slightly.
4. Proposed by the Swedish Institute of Environmental Medicine.

- a 50% reduction in the application in polyurethane foam blowing by the year 2002; a complete phase-out in use of methylene chloride as an auxiliary blowing agent is anticipated by 2007;
- a 90% reduction in emissions from the pharmaceutical coating and chemical intermediates applications by the year 2002;
- in adhesives application, a reduction of 70% in use in the formulated products by 2002;
- in cleaning applications, if more than 10 tonnes are used annually, a 50% reduction by 2002;

These reduction targets will be achieved through improved emission control, source substance substitution, consumer product labelling, improved work practice, restriction on import or development of regulations. If voluntary measures fail to achieve the reduction targets, Environment Canada has indicated that it will consider regulatory measures to mandate the reduction targets.

3.0 Development of an Ambient Air Quality Criterion for Ontario

3.1 Discussion of Regulatory Approaches for Methylene Chloride

The development of ambient air standards and acceptable exposure limits for long-term exposure to methylene chloride in air is based on the avoidance of the non-carcinogenic injury to the liver and other organs as well as on the avoidance of cancer in the liver and the lung. The two approaches are examined separately.

3.1.1 Regulatory Approaches Based on Carcinogenicity Endpoint

There is sufficient evidence to consider methylene chloride as an animal carcinogen. Liver and lung appear to be the main target organs for its carcinogenicity either by inhalation or ingestion route of exposure. Other organs affected include the mammary and salivary glands. Data from epidemiological studies do not provide consistent evidence of carcinogenicity in humans. However, increases of melanoma and cancers in buccal cavity and pharynx, liver and biliary passages, and breast have been observed in some cohort workers exposed to methylene chloride and other solvents (CEPA, 1993).

All jurisdictions consider that methylene chloride is an animal carcinogen. In the U.S.A., carcinogenicity-based guidelines have been developed by jurisdictions where the federal and state governments mandate actions on the issue of human carcinogenicity. Discussions on how most appropriately to employ some of the carcinogenicity-based approaches are ongoing. This is illustrated by the variety of reported unit risks. The CARB (1989) used the data on alveolar and/or bronchiolar adenomas or carcinomas of the lung in mice, observed in a NTP (1986)

inhalation bioassay. They applied combinations of two exposure models (delivered dose based on a physiologically based pharmacokinetic model and high-to-low dose methods) and two mathematical models of cancer formation (linearized multistage and time-dependent multistage). They also presented an estimated increased lifetime cancer risk, using a total PBPK exposure model and a linearized multistage tumour formation model reported by the U.S. EPA (1987, as cited in Commonwealth of Massachusetts (1990)). The unit risk estimates range from $1.0x10^{-6}$ to $10.0x10^{-6}$ tumours per 1 ppb ($3x10^{-7}$ to $3x10^{-6}$ tumours per $\mu g/m^3$, as estimated by CARB, 1989). The California Air Pollution Control Officers Association (CAPCOA, 1993) chose to use $1.0x10^{-6}$ tumours per $\mu g/m^3$. The origin of the New York unit risk ($3.7x10^{-8}$) is not known but appears to be outside the range presented by California. An inhalation unit risk of $4.7x10^{-7}$ tumours per $\mu g/m^3$ was calculated by the U.S. EPA (1991), using a linearized multistage, extra risk model from the combined adenomas and carcinomas in female B6C3F1 mice exposed via inhalation (NTP, 1986). This unit risk incorporates information on pharmacokinetics and metabolism of methylene chloride. The State of Massachusetts (Commonwealth of Massachusetts (1990)) adopted a unit risk of $4.1x10^{-6}$ which, according to the Commonwealth of Massachusetts, was the previous value developed by the U.S. EPA, using an applied dose method.

Environment Canada and Health Canada have assessed the potential cancer risk for methylene chloride under the *Canadian Environmental Protection Act* (CEPA, 1993). Health Canada has developed an inhalation Tumorigenic Concentration 05 (TC_{05}; the concentration in air associated with a 5% increase in incidence or mortality due to tumours) of 2200 mg/m^3. Dividing this TC_{05} value by a margin of 50,000 will provide a benchmark concentration which corresponds to an excess lifetime cancer risk of approximately one in a million (Health Canada, 1996). This TC_{05} was derived from a NTP (NTP, 1986) study based on combined adenomas and carcinomas of the lungs in female mice and combined adenomas and carcinomas in the livers of male rats. The data for the risk estimate was modelled with a PBPK method.

WHO (1987) took the position that because there was no cancer risk estimate available at the time that took into consideration metabolic data, they did not present a cancer risk assessment. Sweden reported that methylene chloride was a carcinogen but adopted the approach of using the NOEL from an animal carcinogenicity study divided by 5000 to develop their guideline.

3.1.2 Regulatory Approaches Based on a Non-carcinogenic Endpoint

Results from short-term studies indicate that methylene chloride has effects on the central nervous system (CEPA, 1993). Data from acute or short-term exposure animal studies indicate that inhaled methylene chloride may induce detrimental effects other than cancer. Adverse effects on the central nervous system, liver, heart, lungs and the kidneys have been observed. Cytological and physiological changes in the liver, kidneys and brain tissue have been reported in chronic exposure studies.

The ACGIH (1991) developed their occupational standard to prevent non-carcinogenic damage to the liver. Their standard was based on the assumption that there would be no concurrent exposure to carbon monoxide in the workplace. In some jurisdictions (Commonwealth of Massachusetts, 1990 and New York, 1991), a short-term limit was based on extrapolation from this occupational standard. It is not possible to scientifically evaluate the methods of extrapolation suggested by New York and Massachusetts. Ontario's current guideline for methylene chloride of 1765 $\mu g/m^3$ (24-hour average limit) is based on the ACGIH TLV and a safety factor of 100 (Rafii, 1988).

The World Health Organization (WHO, 1987) developed a guideline for chronic exposure, based on a study of human volunteers conducted by DiVincenzo and Kaplan (1981). The WHO approach was to protect people from the adverse effects of carbon monoxide, a metabolite of methylene chloride. The WHO chose no more than 0.1% additional carboxyhemoglobin (COHb) as the maximum allowable increase within the human body as a consequence of the metabolism of methylene chloride. Based on the DiVincenzo and Kaplan (1981) study, the WHO calculated that a 1% COHb increase would be associated with a 7.5-hour exposure of about 90 mg methylene chloride. They extrapolated this exposure period to a 24-hour exposure level of up to 28 mg/m^3. They recommended 3 mg/m^3, which was associated with a 0.1% increase in COHb, as the guideline. This approach has the advantage of being based on human data; however, it is potentially problematic because of the extrapolation of a 7.5-hour exposure period to a 24-hour period. The periodic exposure protocol in the study by DiVincenzo and Kaplan allows a 16-hour recovery period between exposures and thus does not reflect the additional stress that continuous exposure may cause.

3.2 Recommendation for an Ambient Air Quality Criterion for Methylene Chloride

Recommendations for new or revised Ontario Ambient Air Quality Criteria (AAQC) and point of impingement (POI) standards are based upon a weight-of-evidence evaluation of available information. The current MOE standards for methylene chloride are as follows; the half-hour POI standard is 5300 $\mu g/m^3$, while the 24-hour average Ambient Air Quality Criterion (AAQC) is 1765 $\mu g/m^3$. Both of these are based on non-cancer human health effects. More recent toxicological information suggests that methylene chloride should be treated as a probable human carcinogen.

A number of agencies including the U.S. Environmental Protection Agency, the California Department of Health Services and the Canadian federal agencies under the *Canadian Environmental Protection Act* have developed cancer risk values for methylene chloride. Health Canada has developed a cancer-based inhalation TC_{05} of 2200 mg/m^3 using data from a study which is also used by the U.S. EPA and the CDHS (Health Canada, 1996). Sweden used a safety factor approach to calculate a cancer-based guideline value of 350 $\mu g/m^3$. Of the criteria reviewed from all the agencies, those developed by the U.S. EPA, CDHS and Health Canada were considered to have the most appropriate rationales. The U.S. EPA and CDHS have

developed lifetime cancer risk estimates and calculated that at a risk level of 10^{-6} the risk specific air concentrations are 2 $\mu g/m^3$ and 1 $\mu g/m^3$ respectively. Both agencies used the same starting data and appear to have used similar models in the development of their respective risk estimates. The U.S. EPA and the CDHS incorporated a physiologically based pharmaco-kinetic method for animal to human dose conversion which was considered a scientifically appropriate approach. The CDHS employed more detailed methods to validate their cancer risk estimation. Both the U.S. EPA and the CDHS have used a linearized multi-stage model to derive their unit risk values.

In contrast, Health Canada has proposed a TC_{05} of 2200 mg/m^3 which corresponds to the concentration at which a 5% increase in incidence of tumour formation or mortality is observed. As interim guidance, Health Canada advises that the application of safety margin of 5,000-50,000 to the TC_{05} provides a comparable level of protection to that associated with levels of lifetime risk generally deemed negligible through low dose extrapolations (i.e. 1/100,000 to 1/1,000,000). Although slightly less conservative than the values developed by the U.S. EPA and the CDHS, the Ministry of the Environment recommends that the TC_{05} developed by Health Canada for methylene chloride be used as the basis for developing an annual average Ambient Air Quality Criterion in Ontario. Applying a safety margin of 50,000 to the TC_{05} of 2200 mg/m^3, an exposure limit of 44 $\mu g/m^3$ can be derived. This concentrations roughly corresponds to an excess lifetime risk estimate of one in a million, a level generally deemed to be negligible.

The relationship between air quality criteria of different averaging times is based on empirically derived factors which are used to relate short-term maxima concentrations to long-term averages. The factors are selected to ensure that if the short-term limit is met (e.g. 24-hour AAQC), air quality guidelines based on longer-term exposure will not be exceeded. The factor typically used to convert from an annual average to a 24-hour maxima is 5 (MOEE 1994c). Depending on the critical end-point being considered other factors may also be employed. Starting with an annual average AAQC of 44 $\mu g/m^3$ for methylene chloride which is based on lifetime exposure, the application of a conversion factor of 5 derives a 24-hour AAQC of 220 $\mu g/m^3$ (Table 2).

Table 2: Recommended AAQCs for Methylene Chloride

AAQC	Annual Average	44 $\mu g/m^3$
AAQC	24-hour Average	220 $\mu g/m^3$

While the 24-hour AAQC of 220 $\mu g/m^3$ is based on the prevention of adverse health effects in the human population, the potential effects of methylene chloride on other terrestrial biota including plants, soil microbes and herbivores were also examined. Limited field and laboratory studies as well as modelling data suggest that exposure to methylene chloride, at the proposed AAQC concentration, is not likely to induce adverse effects in both vegetation and wildlife in Ontario. If

future studies indicate that the proposed air standard for methylene chloride is not protective other terrestrial biota in Ontario, then the basis on which the AAQC is established may need to be reviewed.

4.0 Status of Stakeholder Consultations

In January 1997, the Ministry initiated limited stakeholder consultation on the initial suite of 14 proposed air standards developed under the Standards Plan (MOEE, 1996). During the course of these consultations, written comments were received from several stakeholders expressing concern over the technical ability of flexible foam manufacturers and formulators of certain pharmaceuticals to meet the revised standard. Stakeholders also expressed concern over the potential conflict between the emission reductions being sought under the Strategic Options Process for methylene chloride and revision of ambient air quality standards. In addition, concerns were expressed over the weight given to the carcinogenicity of methylene chloride in the risk assessment for this chemical.

With respect to the weighting given to the evidence of carcinogenicity for methylene chloride, the Halogenated Solvents Industry Alliance petitioned the federal government to re-assess the designation of methylene chloride as toxic under the Canadian Environmental Protection Act. Officials from the Departments of Environment and Health reviewed data submitted in support of the petition and concluded that a re-assessment of the toxicity of methylene chloride was not warranted at this time. The MOE has evaluated the carcinogenic assessments from Health Canada, U.S. EPA and CDHS on methylene chloride and concurs with this decision.

As discussed in Section 2.4, under the *Canadian Environmental Protection Act*, the federal government is targeting a reduction in the use of methylene chloride by 50% - 90% of the 1995 levels by the year 2002 and further reductions are expected beyond this date. The Ministry needs to understand the impacts these reductions will have on predicted ground level concentrations for Ontario sources prior to recommending a revised point of impingement standard for this compound. The Ministry is asking Ontario sources to identify what emission reductions are being achieved through implementation of the recommendations arising from the Strategic Options Process and how this will affect predicted ground level concentrations for methylene chloride. This information will be used to set a revised point of impingement standard for methylene chloride to be implemented on a timetable consistent with the recommendations under the Strategic Options Process.

5.0 Recommendations

Based on the evaluation of recent toxicological information; the ambient air quality guidelines used in other jurisdictions; modelled ground level concentrations from recent applications for Certificates of Approval; the on-going federal Strategic Option Process and the levels of methylene chloride measured in Ontario, the Ministry is proposing:

- an annual average Ambient Air Quality Criterion for methylene chloride of 44 $\mu g/m^3$ (micrograms of methylene chloride per cubic metre of air). This value is based on the health assessment conducted by Health Canada and corresponds to an excess lifetime cancer risk of approximately 1 in 1,000,000;

- a revision of the existing 24-hour Ambient Air Quality Criterion for methylene chloride from its current level of 1765 $\mu g/m^3$ to 220 $\mu g/m^3$.

In light of the reduction strategies for methylene chloride being developed under the Canadian Environmental Protection Act, the Ministry is seeking additional information from stakeholders prior to recommending a revised point-of-impingement standard for this compound. The Ministry is asking Ontario sources of methylene chloride to assess the emission reductions anticipated as a result of strategies being developed under the Canadian Environmental Protection Act. This information will be considered in setting a point-of-impingement standard for methylene chloride to be implemented on a timetable consistent with the recommendations under the Strategic Options Process.

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7.0 Appendix: Agency-Specific Reviews of Air Quality Guidelines

7.1 Agency-Specific Summary: Federal Government of the United States

1. Name of Chemical: methylene chloride

2. Agency: U.S. Environmental Protection Agency

3. Guideline Value(s):
The inhalation unit risk is 4.7×10^{-7} tumours per $\mu g/m^3$. Using a linearized, multistage extra risk model extrapolation procedure, this represents an additional risk of 1 in 100,000 to 1 in 1,000,000 per 20.0 $\mu g/m^3$ or 2.0 $\mu g/m^3$ of lifetime exposure respectively. No ambient air exposure limits are currently promulgated. As of the current date (April, 1997), there is no Reference Concentration (RfC) for chronic inhalation exposure in the IRIS database (USEPA, 1997).

4. Application:
IRIS was developed as a source of consistent risk information on chemicals for use in decision-making and regulatory activities. However, values derived and presented in IRIS do not represent guidelines or standards, in and of themselves. IRIS also contains a summary of current American government regulatory actions under various legislative mandates.

5. Documentation Available:
U.S. EPA, 1997. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, D.C.

Key Reference(s):
Andersen, M.E., H.J. Clewell, III, M.L. Gargas, F.A. Smith and R.H. Reitz, 1987, Physiologically based pharmacokinetics and the risk assessment process for methylene chloride. Toxicol. Appl. Pharmacol., 87:185-205.

NTP (National Toxicology Program), 1986. Toxicology and carcinogenesis studies of dichloromethane (methylene chloride) (CAS No. 75-09-2) in F344/N rats and B6C3F1 mice (inhalation studies). NTP-TRS-306.

6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world, and the published scientific literature, were employed in the development of these values. Both the general assessment methodologies and the chemical-specific information found in IRIS undergo extensive scientific and policy reviews, within both the U.S. EPA and other science-based U.S. regulatory agencies. Information in IRIS is put forward for use after the results of the public review and comments on draft documents/information have been addressed.

7. Status of Guideline:
No guideline exists. The risk estimate discussed is for respiratory exposure from air only.

8. Key Risk Assessment Considerations:
According to the U.S. EPA (1997), the two available studies of occupational health for chemical factory workers exposed to methylene chloride did not show an excess of cancers (Ott *et al.*, 1983; Friedlander *et al.*, 1978; Hearne and Friedlander, 1981). The Ott *et al.* (1983) study was designed to examine cardiovascular effects, not carcinogenicity. In the Friedlander *et al.* (1978) study, exposures were low, but the data provided some suggestion of an increased incidence of pancreatic tumours. This study was recently updated to include a larger cohort, followed through 1984, and an investigation of possible confounding factors (Hearne *et al.*, 1986, 1987). An insignificant excess in pancreatic cancer deaths was observed. An update of the Ott *et al.* (1983) study, based on longer follow-up, indicated possible elevation of liver and biliary tract cancers (TSCA section 8(e) submission no. 8eHQ-0198-0772) (FLWP *et seq.*, 1989).

Animal data were considered sufficient evidence of carcinogenicity in animals. There was an increased incidence of liver (hepatocellular neoplasms) and lung (alveolar/bronchiolar neoplasms) tumours in male and female mice exposed by inhalation (NTP, 1986). Two inhalation studies with methylene chloride have shown an increased incidence of benign mammary tumours in both sexes of two species of rats (Burek *et al.*, 1984; NTP, 1986). Male rats in one study (Burek *et al.*, 1984) had increased salivary gland sarcoma and female rats in the second study (NTP, 1986) had increased leukemia incidence (NTP, 1986). Inhalation exposure of hamsters did not induce neoplasia (Burek *et al.*, 1984).

The inhalation unit risk estimate of 4.7×10^{-7} per $\mu g/m^3$ (last revised February, 1995 by U.S. EPA) was calculated using a linearized, multistage extra risk procedure from the combined adenomas and carcinomas in female B6C3F1 mice exposed via inhalation (NTP, 1986). The unit risk of 4.7×10^{-7} per $\mu g/m^3$, which incorporates information on pharmacokinetics and metabolism of methylene chloride, is approximately nine-fold lower than the previous applied dose estimate (U.S. EPA, 1987a,b). Internal dose estimates were based on the metabolism of methylene chloride by the glutathione-s-transferase pathway, as estimated by the model developed by Andersen *et al.* (1987). The internal dose was corrected for interspecies differences in sensitivity by using the surface area correction factor. Calculation of a slope factor from the unit risk is inappropriate when pharmacokinetic models are used. (When dose-response relationships are figured on the basis of internal or metabolized dose, a slope factor in terms of cancers/(mg/kg/day) represents a back calculation using different absorption assumptions than the pharmacokinetic models. This introduces possible contradictions.) The unit risk should not be used if the air concentration exceeds 2×10^{4} $\mu g/m^3$, since above this concentration the unit risk may differ from that stated. Since the unit risk is based on a pharmacokinetic model, the risk may change with alterations in exposure patterns. Thus, the unit risk presented here may not be applicable to acute, high exposures.

Currently, the U.S. EPA does not have an inhalation RfC for methylene chloride.

9. Key Risk Management Considerations:
None, since no guideline for ambient air exists.

10. Multimedia Considerations of Guidelines:
None are reported.

11. Other Relevant Factors:
As noted in U.S. EPA (1997), methylene chloride was mutagenic for *Salmonella typhimurium* with or without the addition of hepatic enzymes (Green, 1983) and produced mitotic recombination in yeast (Callen *et al.*, 1980). Results in cultured mammalian cells have generally been negative, but methylene chloride has been shown to transform rat embryo cells and to enhance viral transformation of Syrian hamster embryo cells (Price *et al.*, 1978; Hatch *et al.*, 1983). Although chlorinated solvents have often been suspected of acting through a non-genotoxic mechanism of cell proliferation, Lefevre and Ashby (1989) found methylene chloride to be unable to induce hepatocellular division in mice.

7.2 Agency-Specific Summary: State of California

1. Name of Chemical: methylene chloride

2. Agency: State of California (Office of Environmental Health Hazard).

3. Guideline Value(s):
The non-cancer acute reference exposure level (REL) for inhalation is 3500 $\mu g/m^3$, based on a 1-hour exposure. CAPCOA cited U.S. EPA (HEAST, 1991) as the source for this REL. The non-cancer chronic reference exposure level for inhalation is 3000 $\mu g/m^3$, based on protection from central nervous system effects. In 1997, the OEHHA proposed to revise the chronic REL of 3000 $\mu g/m^3$ to 300 $\mu g/m^3$ which is based on effects of methylene chloride on the cardiovascular and the nervous systems. The cancer potency unit risk value (the probability of contracting cancer with constant exposure to an ambient air concentration of 1 $\mu g/m^3$ over 70 years) is $1x10^{-6}$ (0.000001) per $\mu g/m^3$ (CAPCOA 1993). This corresponds to a risk of 1 in 1,000,000 for a 70-year exposure to a methylene chloride concentration of 1 $\mu g/m^3$.

4. Application:
"The intent of the Committee in developing the guideline was to provide risk assessment procedures for use in the Air Toxics 'Hot Spots' Program." (CAPCOA, 1993). This program is based on a California State law: the Air Toxics 'Hot Spots' Information and Assessment Act of 1987 (Health and Safety Code Section 44360 *et seq.*). The act specifies how local Air Pollution Control Districts determine which facilities in their areas will prepare health risk assessments, how such health risk assessments should be prepared and how the results are to be prioritized. These guidelines were prepared to provide consistent risk assessment methods and report presentation to enable: 1) comparisons between facilities, 2) expeditious review of risk assessments by reviewing agencies, and 3) minimal revisions and resubmittals of risk assessments. The various health-based exposure levels developed for and employed in this program should not be employed outside the framework of the program. That is to say, the State of California does not consider them to be general, independent, legally-enforceable air quality guidelines or limit values at this time.

5. Documentation Available:
CAPCOA, 1993. CAPCOA Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association.

CARB, 1989. Technical Support Document: Proposed Identification of Methylene Chloride as a Toxic Air Contaminant. State of California Air Resources Stationary Source Division, Sacramento, CA.

Key Reference(s):
NTP (National Toxicology Program), 1986. Toxicology and carcinogenesis studies of dichloromethane (methylene chloride) (CAS No. 75-09-2) in F344/N rats and B6C3F1 mice (inhalation studies). NTP-TRS-306.

Lewis D.C. and G.V. Alexeeff, 1989. Quantitative Risk Assessment of Non-cancer Health Effects for Acute Exposure to Air Pollutants. In: Proceedings of the Air and Waste Management Association 82nd Annual Meeting. June 1989, Vol. 89-91. 4 p.

6. Peer Review Process and Public Consultation:
Cancer potency slope factors, and acute and chronic reference levels were prepared by the California Office of Environmental Health Hazard Assessment (OEHHA). These, as well as the exposure and health assessments, have undergone public review and comment prior to finalization. Peer-reviewed scientific research data were employed in the development of these values. Under the CAPCOA risk assessment process, each assessment is site-specific, and public notice to all exposed individuals is required when the screening process determines that a significant health risk is associated with emissions from a facility. Public input was obtained in identifying and ranking areas and facilities for risk assessment screening, and, according to the documentation, additional input is expected as the process moves forward.

7. Status of Guideline:
Current, but updates are possible, with new California risk assessment guidelines being considered in the California Senate.

8. Key Risk Assessment Considerations:
The non-cancer acute reference exposure level for inhalation of 3,500 $\mu g/m^3$ is based on human respiratory irritation, using the Defined Practical Threshold (DPT) methodology proposed by Lewis and Alexeeff (1989), which employs the 95% lower confidence estimate on a concentration for a 1% response incidence. This value should protect against perceptible occurrence of observable effects, including irritation, among an exposed human population for a one-hour exposure.

Acute toxicity data indicate that concentrations of 500 ppm may be associated with nervous system depression. Subchronic or chronic exposure of laboratory animals to 500 to 1000 ppm or more has been reported to cause behavioural changes, hepatic dysfunction and, less frequently, lung lesions. There have been relatively few reports of subchronic or chronic toxic effects resulting from exposure to humans. Subchronic and chronic effects reported include alteration in carboxyhemoglobin level, encephalosis, toxemia and bilateral temporal lobe degeneration. According to CARB (1989), in many cases it was unclear whether the reported toxicity was caused by the direct action of methylene chloride or by carbon monoxide, a major product of methylene chloride metabolism. According to CARB, the USEPA (1983) (as cited in CARB (1989)) estimated a no-observed-effect-level (NOEL) from human data (Ott *et al.*, 1983a-e) of

100 ppm (347 mg/m^3). CARB reported that the most sensitive animal study oral NOEL was 5 mg/kg/day (Serota *et al.*, 1986a). Assuming that the toxic effect is independent of exposure route, a NOEL for humans was estimated by CARB to be 5 ppm (approximately 17 mg/m^3). No method for making this extrapolation was presented.

CARB agreed with the U.S. EPA and IARC that methylene chloride was a probable human carcinogen. Several long-term rodent studies have shown that methylene chloride increases tumour rates in some organs, primarily the mouse liver and lung, and the rat mammary gland at concentrations ranging from 1,000 ppm to 4,000 ppm. CARB used the data on alveolar and/or bronchiolar adenomas or carcinomas of the lung observed in mice in the NTP (1986) inhalation bioassay. They applied combinations of two exposure models (delivered dose based on a PBPK model developed by the U.S. Consumer Product Safety Commission (Cohn, 1987) and high-to-low dose methods) and two mathematical models of cancer formation (linearized multistage and time-dependent multistage). They also presented an estimated increased lifetime cancer risk, using a total PBPK exposure model and a linearized, multistage tumour formation model reported by the USEPA (1987). The risks range from 1.0×10^{-6} to 10.0×10^{-6} tumours per 1 ppb (3×10^{-7} to 3×10^{-6} per μg/m^3, as reported by CARB) methylene chloride. The cancer potency unit risk value (the probability of contracting cancer with constant exposure to an ambient air concentration of 1 μg/m^3 over 70 years) chosen was 1×10^{-6} (0.000001) per μg/m^3 (CAPCOA 1993). This corresponds to a risk of 1 in 1,000,000 for a 70-year exposure to a methylene chloride concentration of 1 μg/m^3.

9. Key Risk Management Considerations:
The exposure guidelines were prepared for both non-cancer- and cancer-based endpoints. The cancer-based value is to be used in a screening risk assessment to determine the maximum offsite cancer risk for the exposed human population. The process is not readily comparable to the air quality guideline approach to non-carcinogens. The non-cancer guidelines are based on the most sensitive adverse health effect reported in the scientific literature and are designed to protect the most sensitive individuals in the population.

There are options for addressing the possible economic impacts of controlling methylene chloride emissions. It appears that the options are under local control and are based on local risk and socio-economic analyses, as well as public workshops and hearings. The enforcement mechanism is via operating permits. Thus, the process is primarily directed towards site-specific evaluations and development of further regulatory tools, rather than being enforceable levels in and of themselves.

10. Multimedia Considerations of Guidelines:
In the exposure modelling process, non-inhalation pathways should be considered for a number of substances (specified in Table III-5 in CAPCOA, 1993). Methylene chloride is not one of the substances that require non-inhalation modelling. In the California EPA exposure and health assessments it was acknowledged that exposure pathways other than air (e.g., water and food)

were possible but that, due the lack of quantitative information and the predominance of airborne exposure, other exposure pathways were not considered in the development of the guideline.

11. Other Relevant Factors:
None are reported.

7.3 Agency-Specific Summary: World Health Organization

1. Name of Chemical: methylene chloride

2. Agency: World Health Organization

3. Guideline Value(s):
An air quality guideline of 3,000 $\mu g/m^3$ (24-hour average) is recommended.

4. Application:
"The guidelines are intended to provide background information and guidance to governments in making risk management decisions, particularly in setting standards. It should be strongly emphasized that the guideline values are not to be regarded as standards in themselves." (WHO, 1987, pg. xiii).

5. Documentation Available:
WHO, 1987. Air Quality Guidelines for Europe. WHO Regional Publications, European Series No. 23. World Health Organization, Regional Office for Europe, Copenhagen, Denmark. 426 p.

Key Reference(s):
DiVincenzo, G.D. and C.J. Kaplan, 1981. Uptake, metabolism, and elimination of methylene chloride vapor by humans. Toxic. Appl. Pharm., 59:130-140.

Haun, C.C., E.H. Vernot, K.I. Darmer Jr. and S.S. Diamond, 1972. Continuous animal exposure to low levels of dichloromethane. AMRL-TR-72-13. In: Proceedings of the 3rd Annual Conference on Environmental Toxicology, Wright-Patterson Air Force Base, Ohio, Aerospace Medical Research Laboratory. p. 199-208, as cited in USEPA, 1995 and WHO, 1987.

6. Peer Review Process and Public Consultation:
Scientific background documents were prepared by experts and submitted to working groups consisting of international experts. After a series of meetings and internal and external reviews by experts and representatives of Member States of the Region, the resultant conclusions and recommendations were presented at a final meeting, where they were adopted by consensus of the representatives. In addition, peer-reviewed scientific research data were employed in the development of these documents.

7. Status of Guideline:
No information

8. Key Risk Assessment Considerations:
According to WHO (1987), when the long-term effects of occupational exposure to methylene chloride on the functioning of the central nervous system are considered, the apparent no-

observed-adverse-effect-level (NOAEL) is about 347 mg/m^3 (100 ppm). A similar epidemiological NOAEL can be identified in epidemiological studies on workers in whom exposure in relation to heart disease was evaluated (Ott *et al.*, 1983; Friedlander *et al.*, 1978; Hearne and Friedlander, 1981; Cherry *et al.* (1981). The WHO chose no more than 0.1% additional carboxyhemoglobin (COHb) as the maximum allowable increase as a consequence of the metabolism of methylene chloride. Based on a study of volunteers conducted by DiVincenzo and Kaplan (1981), the WHO calculated that a 1% COHb increase would be associated with a 7.5-hour exposure of about 90 mg/m^3 methylene chloride, which would correspond to a 24-hour exposure level of up to 28 mg/m^3. Three mg/m^3 was associated with a 0.1% increase in COHb. Also, on the basis of animal data showing a LOAEL of 347 mg/m^3 (Haun *et al.*, 1972; Weinstein and Diamond, 1972; Weinstein *et al.*, 1972) and a NOAEL of 87 mg/m^3 (Haun *et al.*, 1972), a value of 3 mg/m^3 is considered appropriate by WHO (1987) for an air quality guideline.

The evidence of carcinogenicity in animals is sufficient for methylene chloride and evidence in humans is inadequate.

9. Key Risk Management Considerations:
The guideline value is applicable to both indoor and outdoor situations.

10. Multimedia Considerations of Guidelines:
Human exposure from air, drinking water and diet was considered in the evaluation, but this did not specifically contribute to the determination of the final guideline value.

11. Other Relevant Factors:
WHO (1987) stated that because there was no cancer risk estimate available at the time that took into consideration metabolic data, they did not present a cancer risk assessment.

7.4 Agency-Specific Summary: The Netherlands

1. Name of Chemical: methylene chloride

2. Agency: Netherlands Ministry of Housing, Spatial Planning and the Environment

3. Guideline Value(s):
The maximum acceptable concentration (MAC), an occupational guideline, is 350 mg/m^3. The maximum emission concentration (MIC) is 7.5 $\mu g/m^3$. The target value is 20 $\mu g/m^3$.

4. Application:
Limit values are non-statutory environmental quality objectives that are considered policy guidelines. They should not be exceeded and should be considered as requirements to be met. These effects-oriented guidelines may be used simultaneously with source-oriented emission criteria, although it is the latter that are the primary regulatory mechanism. If effects-oriented guidelines continue to be exceeded, then existing source-oriented emissions criteria will be lowered to bring ambient levels below the effects-oriented guidelines. A maximum acceptable concentration (MAC) is the maximum acceptable concentration of a gas, vapour, or mist of a substance in a workplace.

5. Documentation Available:
Netherlands MHSPE, 1994. Environmental Quality Objectives in The Netherlands. A review of environmental quality objectives and their policy framework in The Netherlands. Risk Assessment and Environmental Quality Division, Ministry of Housing, Spatial Planning and the Environment (MHSPE), The Hague, The Netherlands. 465 p.

NeR Staff Office, 1992. Netherlands Emission Regulations - Air. Netherlands Emission Regulations Staff Office, Bilthoven, The Netherlands. 81 p. + Appendices.

Earlier air criteria documents or more recent integrated criteria documents are available for priority substances such as methylene chloride, but only in Dutch.

6. Peer Review Process and Public Consultation:
No specific information on this issue was presented in the available English language documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
No information available

9. Key Risk Management Considerations:
National limit values include consideration of environmental, economic and social interests, as well as technical options. Specific information on such details was not presented in the available documentation.

10. Multimedia Considerations of Guidelines:
Multimedia exposure was not considered in the development of the current air guideline limits; however, intercompartmental criteria which address this problem are being developed. A specific schedule for revisions based on this process has not been announced, and methylene chloride is not on the initial list of chemicals to be considered.

11. Other Relevant Factors:
No information

7.5 Agency-Specific Summary: Swedish Institute of Environmental Medicine

1. Name of Chemical: methylene chloride

2. Agency: The values reported below are those recommended by the Swedish Institute of Environmental Medicine. According to Dr. K. Victorin of the Swedish Institute of Environmental Medicine (pers. comm.) no official Swedish air quality guidelines have been promulgated by the Swedish Environmental Protection Agency.

3. Guideline Value(s):
The recommended value is a long-term average of 350 $\mu g/m^3$.

4. Application:
Used on an *ad hoc* basis.

5. Documentation Available:
Victorin, K., 1993. Health effects of urban air pollutants: guideline values and conditions in Sweden. Chemosphere, 27:1691-1706.

Key Reference(s):
Fransson, R. and U.G. Ahlborg, 1990. Medicinska och hygieniska effekter av diklormetan, trikloreten och tetrakloreten i omgivningsluft. Insitutet för miljömedicin: Karolinska institutet, Stockholm, Sweden. (Swedish documentation, English summary).

6. Peer Review Process or Public Consultation:
No information was available in the documentation.

7. Status of Guideline:
It has no official status but has been used on an *ad hoc* basis by Swedish regulators.

8. Key Risk Assessment Considerations:
The following information was taken from the English summary in Fransson and Ahlborg (1990). No references to the studies cited are given. Data support the conclusion that methylene chloride is carcinogenic in animals and mutagenic. Risk assessment was therefore based on carcinogenicity. The lowest air concentration where carcinogenic effects were reported in animals was 500 ppm. A safety factor of 5000 was applied and the medically-based, low risk level was calculated to be 100 ppb (350 $\mu g/m^3$).

9. Key Risk Management Considerations:
The estimate is considered to be similar to that in WHO (1987).

10. Multimedia Considerations of Guidelines:
Based on human health considerations for respiration only.

11. Other Relevant Factors:
No information

7.6 Agency-Specific Summary: New York State

1. Name of Chemical: methylene chloride

2. Agency: New York State

3. Guideline Value(s):
The recommended 1-hour average is 41,000 $\mu g/m^3$ based on an extrapolation from an occupational exposure guideline. The recommended annual average is 27 $\mu g/m^3$ based on a unit risk of 0.000000037 tumours per $\mu g/m^3$ and a cancer risk level of $1x10^{-6}$.

4. Application:
". . . they are primarily intended for use in conjunction with the permitting authority and regulatory concerns found in 6NYCRR Parts 200, 201, 212 and 257." (NYDEC, 1991, p. 1). These regulations refer specifically to construction and operation (Certificate to Operate) permits for any sources of air contamination. Rather than being employed as legally enforceable, ambient air quality standards, the guidelines are to be employed to aid in the regulatory decision-making process. This process includes the classification of chemicals into groups of high, moderate and low toxicity. The regulatory screening process considers the toxicity classification and the emission rate potential from a facility. An air emission dispersion model is also specified in the process to guide regulators in their assessment of chemical emissions from sources of interest. Both long-term and short-term effects are considered.

5. Documentation Available:
NYDEC, 1991. New York State Air Guideline -1. Guidelines for the Control of Toxic Ambient Air Contaminants. Draft. New York State Department of Environmental Conservation, Albany, N.Y. 20 p. + Appendices.

Key Reference(s):
ACGIH, 1991. Documentation Of The Threshold Limit Values for Substances in Workroom Air (6th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

6. Peer Review Process and Public Consultation:
The scientific documents prepared by New York State employed peer-reviewed data and models, as well as the professional judgements of its scientific staff. There are opportunities for public comment on guidelines and the guideline development process, but specific information on the process for methylene chloride was not presented in the available documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
New York State (1991) has classified the toxicity of methylene chloride as moderate. Compounds given the designation of moderate are animal oncogens, developmental and reproductive toxicants, genotoxic chemicals and other chemicals posing a health hazard to humans. For compounds in this classification, the short-term guideline was developed by dividing a chosen occupational standard by 4.2. In the case of methylene chloride, New York used the occupational standard of 174 mg/m^3 (ACGIH, 1991).

The long-term guideline was developed by calculating the exposure at an acceptable individual risk level of $1x10^{-6}$. They reported that concentration as 27 $\mu g/m^3$. From this information, the unit risk was estimated to be $3.7x10^{-8}$ additional tumours per $\mu g/m^3$.

9. Key Risk Management Considerations:
A specific computer model and guidance manual are provided for use of the guidelines in impact screening analyses as employed in the permitting process. The latest version of Appendix B of the New York State Air Guide -1 is dated April 4, 1994.

10. Multimedia Considerations of Guidelines:
Considers human airborne exposure only

11. Other Relevant Factors:
No information

7.7 Agency-Specific Summary: State of Massachusetts

1. Name of Chemical: methylene chloride

2. Agency: Commonwealth of Massachusetts

3. Guideline Value(s):
A 24-hour ceiling limit is 94.5 $\mu g/m^3$ based on the threshold effects exposure limit (TEL) which is an extrapolation from an occupational exposure guideline. The allowable ambient limit (AAL) is 0.24 $\mu g/m^3$ for an annual (1 year) averaging time and is based on carcinogenic effects. The unit risk is 0.0000041 tumours per $\mu g/m^3$ and the cancer risk level is $1x10^{-6}$.

4. Application:
". . . the Division of Air Quality Control, which is responsible for implementing the Department's air programs, plans to employ the AALs in the permitting, compliance, and enforcement components of the Commonwealth's air program in general, and the air toxics program in particular." (Commonwealth of Massachusetts, 1990, Volume 1, pg. ix). The primary goal is to "protect the public health and welfare from any air contaminant causing known or potentially injurious effects". The ambient air levels developed in this process should not be considered legally enforceable, air quality standards since they deal only with health-related matters and contain no consideration of technological, economic or enforcement concerns. Rather, they should be employed as guidelines in the development of subsequent regulatory action which does contain a broad consideration of all relevant concerns.

5. Documentation Available:
Commonwealth of Massachusetts, 1990. The Chemical Health Effects Assessment Methodology and the Method to Derive Allowable Ambient Limits, Volumes I and II. Commonwealth of Massachusetts, Department of Environmental Protection, Boston, MA.

Key Reference(s):
ACGIH, 1986. Documentation Of The Threshold Limit Values for Substances in Workroom Air (5th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

U.S. EPA (U.S. Environmental Protection Agency), 1985. Addendum to the health assessment document for dichloromethane (methylene chloride). Updated carcinogenicity assessment of dichloromethane (methylene chloride). EPA-600/8-82/004F. EPA, ORD, OHEA, Washington, D.C., as cited in U.S. EPA, 1995.

6. Peer Review Process and Public Consultation:
Peer-reviewed, scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world, and the published scientific literature, were employed in the development of these values. Specifically, evidence from the

International Agency for Research on Cancer (IARC), the American National Toxicology Program (NTP) and the U.S. EPA was employed. As guidelines, the process used and values generated are not subject to the extensive review and consultation that air quality standards would be subjected to, but external peer reviews were carried out, and public input was solicited through at least two public meetings on the Massachusetts methodology and guideline document (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.)

7. Status of Guideline:
Current. Although guideline values are periodically updated, revisions to the current value for methylene chloride are not under consideration (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.)

8. Key Risk Assessment Considerations:
The State of Massachusetts has a method for establishing a limit that assumes the compound has a threshold for adverse effects. In the case of methylene chloride, the 1986 ACGIH occupational limit, reported to be 174 mg/m^3 (ACGIH, 1986 (reported as 173.7)), was divided by several factors that attempt to extrapolate from a worker health-based limit to a public limit that protects children and other sensitive individuals. The uncertainty factor incorporates judgments about the amount of information on the toxicity of the compound, the differences between body sizes and weights between adult males and children, and an assumption about the relative contribution of the compound to the total exposure from air. The total uncertainty factor in the case of methylene chloride was 1838.1, which produced a 24-hour ceiling limit of 94.5 $\mu g/m^3$.

The State of Massachusetts accepted the U.S. EPA designation of methylene chloride as a probable human carcinogen and chose to accept the individual unit risk of $4.1x10^{-6}$ (0.0000041) additional tumours per $\mu g/m^3$ which was promulgated by the U.S. EPA at that time (U.S. EPA, 1985). They noted that the U.S. EPA had revised their risk assessment to reflect pharmacokinetic data but that this revised risk assessment was not yet formally adopted by the U.S. EPA. No reference was given for this information.

9. Key Risk Management Considerations:
The primary objective of the process is the protection of public health. The Massachusetts system uses hazard assessment only and does not use the number of exposed individuals as a criterion for regulatory action. Furthermore, the selection of the AAL is based on the most sensitive effect. The U.S. EPA's cancer unit risk values (U.S. EPA, 1985) and the ACGIH occupational TLV values were adopted for regulation development purposes. For carcinogens, a maximum allowable increase in risk associated with exposure to a chemical was set at one per million ($1x10^{-6}$) for a 70-year lifetime.

10. Multimedia Considerations of Guidelines:
A generic allowance was made for contributions from sources other than respiration: "A relative source contribution factor of 20% is also included to account for sources other than air." (Commonwealth of Massachusetts, 1990, pg. viii).

11. Other Relevant Factors:
The State of Massachusetts intended to adopt the new individual unit risk estimate by the U.S. EPA after formal acceptance. If the unit risk of 4.1×10^{-7} is used the AAL would be 2.4 $\mu g/m^3$.